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10/720,086	11/25/2003	Brian J. Lancaster	CRNI.111056	4915

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EXAMINER	
LUBIN, VALERIE	
ART UNIT	**PAPER NUMBER**
3626	

MAIL DATE	DELIVERY MODE
04/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/720,086	LANCASTER ET AL.	
	Examiner	Art Unit	
	VALERIE LUBIN	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-15,17-25 and 29-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-15,17-25 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

2. Claims 1-4, 6-15, 17-25, 29-34 are pending

For reference purposes, the document paper number is 20100413

Response to Arguments

3. Applicant's arguments filed 02/09/2010 regarding claims 1-4, 6-15, 17-25, 29-34 have been fully considered but they are not persuasive.

4. For claim 1, Applicant argues that Rosenfeld doe not describe key performance indicators. Examiner respectfully disagrees and refers Applicant to Rosenfeld col. 43 lines 11-43 which discusses the use of key indicators to perform data analysis/comparison. Rosenfeld does not discuss the type of key performance indicators; however, Shen covers the use of key indicators to project facility-wide outcomes which such indicator being at least one of a financial, operational or clinical metric (¶ 133, 134: "clinical outcomes…financial outcomes…outcomes comparing with benchmarks or organizational projected goals…").

5. Applicant also argues that Shen's disclosure is not enabling; however Applicant has failed to persuasively show how and why the prior tar is not enabling. Examiner maintains that the prior art is clear and elaborate enough as to enable one of ordinary skill in the art to perform the functions of the disclosed system without undue experimentation.

6. A new rejection of claims 12-15, 17-22 under 35 USC § 101 is necessitated in light of Applicant's amendments.

7. The rejection of claims 12-15 and 17-25 under 35 USC § 112, 2nd paragraph is withdrawn; however, a new rejection of claims 12-15, 17-22 is necessitated in view of Applicant's amendments.

8. A new rejection of claims 29-34 under 35 USC § 112, 1st paragraph is necessitated in view of Applicant's amendments.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 12-15, and 17-22 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

11. Independent claim 12 is directed to “One or more computer-readable media…” which when given the broadest reasonable interpretation covers forms of non-transitory tangible media and transitory propagating signals per se. The claim should specifically recite only statutory embodiments by adding language such as "non-transitory" to the claim.

Claims 13-15, and 17-22 are also rejected under the above analysis.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 29-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was

not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

14. Independent claim 29 recites inference engine means that “quantify at least one opportunity for improvement in patient mortality or patient morbidity and an opportunity for financial change ..." Applicant's disclosure does not provide any support for quantifying an improvement in patient mortality or morbidity.

Claims 30-34 are rejected under the above analysis.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 12-15 and 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Independent claim 12, recites, “providing an indication of a second key performance indicator that is most significant to a first user; wherein the second key performance indicator is the same or different from the first key performance indicator…” It is unclear what is being claimed by “most significant" as Applicant does not provide a standard measure of significance. For examining purposes, the limitation shall be interpreted as

"providing a second key performance indicator that is the same or different from the first key indicator…"

Claims 13-15 and 17-22 are rejected under the above analysis.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-15, 17-22 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld et al. U.S. Patent No. 6,804,656 in view of Shen Pre-Grant Pub No. 2003/0212580.

20. With regards to claim 1, Rosenfeld teaches a system comprising a first interface to a clinical data store (Col. 19 lines 2-44); a second interface to a knowledge base (Col. 5 lines 11-22; col. 22 lines 15-19); and an inference engine to selectively perform comparative analysis of the clinically related data against the knowledge base (Col 4. lines 8-13; col. 5 lines 11-22). Rosenfeld also recites key performance indicators (Col. 42 lines 11-43

Rosenfeld does not specifically disclose that the comparative analysis projecting at least one facility-wide outcome based on an analysis of the clinically related data and a clinical guideline selected from the knowledge base, predicting an operational effect of altering a guideline or a policy being used in a clinical facility or organization and quantifying an opportunity for improvement if an altered guideline or policy is used in a clinical facility or organization. However, Shen does recite projecting at least one facility-wide outcome (¶ 133). Shen recites a facility-wide outcome and "simulation and prediction of modified process outcomes with new organizational goals; and dissemination of new policies/guideline/process through the organization" which is the equivalent of quantifying outcomes when altered policies or guidelines are implemented. Shen also discloses in ¶ 133 and 134 financial and clinical outcomes or performance indicators. It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections. Furthermore, Examiner notes that the language, "quantifying at least...when the altered…" is optional and according to the MPEP, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." MPEP 2106.II.C

Claim 12 is rejected under the analysis of claim 1, as Rosenfeld also recites generating an alert that notifies a user in the event that a guideline or threshold is violated (Col. 21 lines 45-47). Furthermore, the limitation is optional.

Claim 29 are rejected under the analysis of claim 1.

21. With respect 2, Rosenfeld teaches a data warehouse (Col. 7 lines 7-10).

Claims 13 and 30 are rejected under the analysis of claim 2.

22. Claim 3 is rejected as Rosenfeld teaches the data warehouse storing clinically related data from at least one clinical facility (Abstract; Fig. 8A item 9034; Fig. 8B item 9038).

Claims 4, 14 and 15 are rejected under the analysis of claim 3.

23. With respect to claim 5, Rosenfeld teaches the comparative analysis comprising an analysis of at least one key performance indicator (Col. 43 lines 11-53).

Claim 31 is rejected under the analysis of claim 5.

24. Claims 6 and 7 are rejected as Rosenfeld teaches the knowledge base comprising a set of clinical guidelines with best practices (Col 3. lines 51-55; col. 5 lines 11-22; col. 26 lines 8-17).

Claims 17, 18 are rejected under the analysis of claims 6 and 7.

25. For claim 8, Rosenfeld recites best practices data comprising pharmaceutical and medical procedure information (Col. 7 lines 24-67); and he discloses historical files (Col. 20 lines 42-46). Shen also recites the use of historical outcome information (¶ 134). It would have been obvious to one of ordinary skill to combine the teachings of Rosenfeld and Shen to include historical outcomes information in best practices for reuse when appropriate.

Claim 19 is rejected under the analysis of claim 8.

26. Claim 9 is rejected as Shen discloses the facility-wide outcome comprising a financial outcome, an operational outcome or a clinical outcome corresponding with a plurality of patients or a combination thereof (¶ 123). It would have been obvious to one of ordinary skill in the art to combine the teachings of Rosenfeld with those of Shen in order to produced realistic projections.

Claims 20 and 32 are rejected under the analysis of claim 9.

27. With respect to claim 10, Rosenfeld discloses maintaining a performance mortality measure (Col. 16 lines 4-6); and outcome algorithms for antibiotic cost information (Col. 7 line 31). Shen also recites clinical cost information (¶ 20, 112). A predictable result of Rosenfeld and Shen would be to include whatever information necessary (e.g. patient mortality and morbidity information, clinical cost information etc.) for informational purposes. (KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007)). Furthermore, the data contained in the outcome is non-functional descriptive material that does not further limit the process of claim 1 (In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01 II).

Claims 21 and 33 are rejected under the analysis of claim 10.

28. Claim 11 is rejected as Rosenfeld teaches storing the comparative analysis (col. 20 lines 1-5).

Claims 22 and 34 are rejected under the analysis of claim 11.

29. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen Pre-Grant Pub No. 2003/0212580.

30. With respect to claim 23, Shen discloses a method comprising the steps of receiving a selection of one a plurality of policies and procedures stored within a knowledge base (¶ 20, 57, 85); accessing clinically related data corresponding with a plurality of patients (¶ 100); selectively performing comparative analysis of the clinically related data against the first selected policy or procedure to provide an indication as to whether the first selected policy or procedure has been attained by a medical facility (¶ 100, 110). Furthermore, the language, "to provide an indication…" is directed to the intended result of the step of selectively performing a comparative analysis, and it has been held that a "clause in a method claim is not given weight when it simply expresses the intended result of a process step positively recited" (*Minton v. Nat'l Ass'n of Securities Dealers, Inc.*, 336 F.3d 1373, 1381, 67 USPQ2d 1614, 1620 (Fed. Cir. 2003)). Examiner also notes that the type of clinically related data accessed does not further limit the method of claim 23

Shen also recites using selected policy or procedure and clinically related data corresponding with a plurality of patients to perform a predictive analysis that projects at least one operational, financial or facility-wide outcome (¶ 46,133); altering metrics, guidelines or policies (¶ 133, e.g. "simulation and prediction") with metrics relating to tests leading to a surgery (¶ 9, 72). Additionally, Shen recites a facility wide outcome and "simulation and prediction of modified process outcomes with new organizational goals; and dissemination of new policies/guideline/process through the organization" which is the

equivalent of quantifying outcomes when altered policies or guidelines are implemented. Examiner notes that the quantifying step of the sixth limitation and subsequently, the seventh limitation of the claim are optional, and according to the MPEP, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation." MPEP 2106.II.C. Shen also recites the determining the impact of altered guidelines or policies on costs (¶ 20, 115, 134)

Shen does not specifically recite receiving a second selection of one of the plurality of policies; however, this is merely a duplication of the first limitation and it has been held that the "mere duplication of parts has no patentable significance unless a new and unexpected result is produced" (In re Harza, 274 F.2d 669, 124 USPQ 378 (CCPA 1960)).

31. Claim 24 is rejected, as Shen recites accessing a data warehouse (Abstract, ¶ 42).

32. Claim 25 is rejected, as Shen discloses performing an analysis of at least one key performance indicator (Abstract, ¶ 12).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE LUBIN whose telephone number is (571)270-5295. The examiner can normally be reached on Monday-Friday 7:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. L./
Examiner, Art Unit 3626

/C. Luke Gilligan/
Primary Examiner, Art Unit 3626